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| 10/598,355 | 05/12/2008 | Lawrence Solomon | SLP-054 | 2979 |

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| EXAMINER | |
|---|---|
| LOVE, TREVOR M | |
| ART UNIT | PAPER NUMBER |
| 1611 | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/598,355 | SOLOMON ET AL. | |
| | Examiner | Art Unit | |
| | TREVOR M. LOVE | 1611 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *04/22/2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1,3,4,6-47 and 49-52* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,4,6-47 and 49-52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

Acknowledgement is made to Applicant's response filed 04/22/2009.

Claims 1, 3-4, 6-47, and 49-52 are currently pending and are under consideration.

Any rejection and/or objection not explicitly stated or re-stated herein is to be considered withdrawn.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

**Claims 11 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.**

Claims 11 and 12 recite the limitation "said third segment". Based on Applicant's most recent amendment to claim 1 there is insufficient antecedent basis for this limitation in the claim.

### *Claim Rejections - 35 USC § 103*

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

**Claims 1, 3-4, 6-10, 13-34, 39-47, and 49-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lieberman (Pharmaceutical Dosage Forms – tablets, 1990) in view Geller (U.S. Patent number 3,927,194).**

With regard to independent **instant claim 1**, Lieberman teaches a pharmaceutical dosage form with layers. Said composition can have active layers 1 and 3 wherein layer 2 is an inert barrier layer (see Lieberman first paragraph under “IV. Layer Tablets”). Lieberman further teaches that it is known to place scores on tablets to allow for manual breakage, however, Lieberman acknowledges that traditional scores result in significant variation in drug dose (see Lieberman, point number 4 under "Properties of Tablets"). Geller teaches a score that is up to 2/3 the depth of a tablet which allows for breakage of a tablet into substantially equal parts (see Geller, claim 1 and figures 1, 2, 4, and 5).

With regard to independent **instant claim 8**, Lieberman teaches a pharmaceutical dosage form with layers. Said composition can be a tri-layer tablet wherein said three segments differ in that each segment is either immediate, slow, or intermediate release (see Lieberman first paragraph under “IV. Layer Tablets”), this allows for all three layers to have the same active while being compositionally distinct.

Lieberman, in section “IV. Layer Tablets” first paragraph, discloses layered tablets wherein the granulation layers are "sandwiched" on top of each other, and the edges are exposed, this reads on **instant claim 25**. Said layered tablets are disclosed as 2 or 3 layers of granulation compressed together wherein said layers can have different coloring to allow for unique tablet identification, this reads on **instant claim 19**. Lieberman teaches that layered dosage forms have the advantage of being able to separate two incompatible substances with an inert barrier, or instead of modifying the active ingredient, they can be used to modify the release profile, each layer can

comprise components that determine immediate, intermediate, or slow release of the active, this, in combination with Geller, reads on **instant claims 4, 22, and 46-47**. Furthermore, Lieberman discloses that the layered tablet method allows for the weight of each layer to be accurately modified, this would also allow for the thickness of the individual layers to be regulated and modified. The multilayer tablets are also disclosed as being capable of having “distinctive markings” impressed on the surface. Lieberman, in the section discussing the "Properties of Tablets" discloses under point "4" that tablets can contain markings. Said markings may appear as a score or crease across the face, which is intended to permit breaking the tablet into equal parts for administration. Lieberman, however, states that substantial variation can occur in manually broken tablets.

Lieberman fails to directly envisage that the score on the multilayer tablet extends at least 70% of the distance of the first segment of said multilayer tablet.

Geller teaches a tablet for breaking into smaller dosages which is scored sufficiently to form a groove which is 1/3 to 2/3 the depth of the total tablet thickness (see claim 1), this can be greater than 50%, and therefore reads on **instant claims 3, 6-7, 14, 24, 32, 45, and 49**. This groove being designed to facilitate separation into subdivisions containing substantially equal amounts of pharmaceutically active ingredients (see claim 1 and figures 1, 2, 4, and 5), this reads on **instant claims 13, 17, 20, 26, 42, and 44**.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize the groove of Geller in the tablets of Lieberman. One

would have been motivated to do so with a reasonable expectation of success since both Lieberman and Geller teach that tablets can be scored in order to facilitate breaking the tablet into equal parts for administration.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have all three layers be directly atop one another. One would have been motivated to do so since Lieberman teaches a two or three layer composition wherein the components have the appearance of a sandwich because the edges of each layer are exposed (see page 274, section IV first paragraph).

It further would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the contents of the different layers. One would have been motivated to use different actives in the different layers since Lieberman teaches one motivation for layering is the separation of incompatible layers, which would obviously contain different substances, wherein at least three layers would be necessary to achieve effective separation (see page 274, section IV, first paragraph). In the same paragraph Lieberman teaches that another motivation for layering is varying the speed of release of the different coatings. Lieberman directly teaches three coatings, all with different release rates: immediate, slow release, and intermediate release. Lieberman also teaches that the weights of the layers can be varied. These teachings of Lieberman read on tablets with varying concentrations with three different actives (or non-actives) with three different release rates, tablets with three of the same actives with different (or the same) release rates (such as **instant claim 9 and 15-16**), or combinations thereof (such as **instant claim 10, 18, and 28-29**).

With regard to the difference between the 70% of the instant claims and the 66.66% of Geller, MPEP 2144.05 states that "where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). It would have been obvious for one of ordinary skill in the art at the time the invention was made to desire a score that was as far through the tablet as is possible. One would be motivated to have a deeper score to facilitate breakage of said tablet at said score.

With regard to **instant claims 21-23, 27, 30, 31, 33, 34, 39-41, 43, and 50**, the thickness of the layers is not specified, however, the ability to modify the weight of the different layers is taught Lieberman. It would have been obvious to one of ordinary skill in the art to vary the thickness of each layer; this is directly taught by Lieberman (see page 274, section IV, first paragraph). One would have been motivated to do so to minimize the amount of the crucial dosage layers that are involved in the breaking of the tablet, leaving non-crucial layers, such as layers 2 or 3 to be broken through. This reduces the variability in the concentration of the components of the top layer. There would be a reasonable expectation of success in varying the thickness, which would vary the amount of each layer affected by the score, since Lieberman directly teaches that the layers can be varied.

With regard to whether the amount of an active present is therapeutically effective is dependent on the condition being treated not the size of the tablet.

Therefore the amounts and percentages described by Lieberman would necessarily be therapeutic in some scenarios.

*Applicant's Arguments*

Applicant argues in the response filed 04/22/2009 that the composition of claim 1 (a)(i) is directed to a bi-layer layer tablet which contains an active segments and an immediate release inactive segment. Applicant argues that there is nothing in the prior art which teaches said limitations. Applicant argues that the instant immediate release layer serves a unique purpose of providing a support layer so the active layer may be scored substantially through its entire thickness. Applicant argues that nowhere in Lieberman does Lieberman teach or suggest an inactive immediate release layer adjacent to an active layer in a bi-layer tablet (see Remarks, page 13, lines 4). Applicant further argues that Lieberman does not envision tablets having the specific configuration of part (c) of claim 1. Applicant further argues that there is no reason to modify Lieberman with the Geller score technique, furthermore, Applicant states that alone or in combination Lieberman and Geller fail to teach the instant tablets. Applicant's argues that Lieberman in view of Geller fails to disclose anyone of the embodiments of claims 8 or 22. Applicant alleges that since it is Applicant's position that Geller does not cure the deficiencies of Lieberman, the dependent claims are also improperly rejected.

*Response to Arguments*

Applicant's arguments have been fully considered and are not found persuasive. It is noted that Applicant repeatedly utilizes the term "or" in the instant claims. For

example, as can be seen in instant claim 1, the recitation of the term "or" allows for claim 1 and any dependent claims therefrom to be rejected without necessarily meeting the limitations of (a), (b), or (c), with the proviso that at least one of (a), (b), or (c) have been met. It is respectfully noted that the many of Applicant's arguments are directed to Lieberman or Geller failing to teach specific limitations which are optional, and therefore, are not required in order make a proper rejection. For example, Applicant argues that nowhere in Lieberman does Lieberman teach or suggest an inactive immediate release layer adjacent to an active layer in a bi-layer tablet, however, no where in the instant claims does Applicant specifically *require* the limitations of an inactive immediate release layer adjacent to an active layer in a bi-layer tablet. Furthermore, as identified above, Lieberman in view of Geller teaches at least (c) in claim 8, and (b) of claim 22 wherein it is noted that (b) does not require the actives to be compatible, and as discussed above, varying the thickness of each layer of the tablet is directly taught in Lieberman.

With regard to Applicant's argument that there is insufficient motivation to combine Lieberman and Geller it is noted that Lieberman directly teaches the use of a score, and further identifies the deficiency therewith, specifically, a lack of reliability with regard to the precise dosage obtained. Geller cures said deficiency by utilizing a score that is 2/3 the depth of the total thickness of the tablet. Sufficient motivation exists to combine Lieberman with Geller since Geller is directly curing a deficiency identified by Lieberman, utilizing a score which is directly taught by Lieberman. In view of the

arguments above, and the response thereto, Applicant's arguments are not found persuasive.

**Claims 35-38 and 51-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lieberman (Pharmaceutical Dosage Forms – tablets, 1990) and Geller (U.S. Patent number 3,927,194) in view of Löfroth et al (U.S. Patent number 6,827,947).**

The teachings of Lieberman and Geller are set forth above.

Lieberman in view of Geller fails to directly disclose that the composition is placed in a sachet. Lieberman in view of Geller further fails to teach that the active is metoprolol, and that the active is treating a cardiovascular condition, psychiatric condition, diabetes, thyroid disorder, pain, or thrombotic disorder.

Löfroth teaches an oral dosage form that has modified release properties, wherein the dose size is adaptable, and the tablet is divisible, this reads on **instant claim 37**. Löfroth teaches that the active is preferably metoprolol, which aids in the treatment of cardiovascular disease (see column 1, lines 44-52 and column 6, lines 37-56), this reads on **instant claim 38 and 51**. Said composition is taught to be coated and then placed into a sachet (see column 5, lines 7-11), this reads on **instant claims 35-36**.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize metoprolol in the invention of Lieberman in view of Geller. One would have been motivated to do so since Löfroth teaches that metoprolol is

known to be successful in divisible tablets that have modified release profiles. There would be a reasonable expectation of success in the combination since Löfroth teaches that metoprolol is known to work in tablets that are to be divided and have modified release profiles.

With regard to **instant claim 52**, the location of the actives, and the amounts thereof, are taught by Lieberman as being readily modifiable. Furthermore, Lieberman teaches that drugs can be separated to allow for different rates of release, therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have two layers that comprised metoprolol with different release rates for each layer.

*Applicant's Arguments*

Applicant argues in the response filed 04/22/2009 that Löfroth fails to cure the deficiencies of Lieberman, particularly those that Geller has allegedly failed to cure (see Applicant's arguments above).

*Response to Arguments*

Applicant's arguments have been fully considered and are not found persuasive. Applicant's argument that Löfroth fails to cure the deficiencies of Lieberman, specifically those that Applicant believes are not cured by Geller with regard to the independent claims, is not found persuasive in view of the response to arguments set forth above. It is noted that Löfroth is not required to cure deficiencies in Lieberman which have already been met by secondary reference Geller.

***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

**Claim 1 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/598,344.** Although the conflicting claims are not identical, they are not patentably distinct from each other.

The copending application teaches in copending claim 1 an immediate release pharmaceutical tablet having a first segment which contains a drug, a score, and a second segment, wherein either said second segment does not contain a drug or said score extends at least 70%, this reads on **instant claim 1** since instant claim 1 does not specify how the first segment is altered to achieve said release, and therefore, making a composition be immediate release could be altering the release.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

*Applicant's Arguments*

Applicant fails to substantially argue the nonstatutory obviousness-type double patenting rejection in the response filed 04/22/2009.

*Response to Arguments*

In light of Applicant's failure to substantially argue the nonstatutory obviousness-type double patenting rejection in the response filed 04/22/2009, the rejection is maintained.

## ***Conclusion***

No claims allowed. All claims rejected. No claims objected.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TREVOR M. LOVE whose telephone number is (571)270-5259. The examiner can normally be reached on Monday-Thursday 7:30-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TL

/Sharmila Gollamudi Landau/
Supervisory Patent Examiner, Art Unit 1611